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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,737	01/30/2006	Chris Leeflang	GC787-2-PCT	9805

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EXAMINER
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VOGEL, NANCY TREPTOW

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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03/31/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,737	<b>Applicant(s)</b> LEEFLANG ET AL.	
	<b>Examiner</b> NANCY VOGEL	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/06</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1-8 are pending in the case.

Receipt of the Information Disclosure Statement on 2/27/06 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and by dependence claims 2-5 are vague and indefinite in the recitation of "said intermediate fragments" in part (b). It is unclear which of the intermediate fragments recited in part (a) is intended. Part (a) recites more than one intermediate fragments.

Claims 1 and by dependence claims 2-5 are vague and indefinite in the recitation of "said partially overlapping intermediate fragments further comprising a first intermediate fragment and a second intermediate fragment" since it is not clear how a fragment can comprising another fragment.

Claims 4 and 5 recite the limitation "said forward digestion site primers..." (claim 4) and "said reverse digestion site primers..." (claim 5) in lines 1-2. There is insufficient antecedent basis for this limitation in the claim on which the claims depend, i.e. claim 3 and indirectly claim 1. There is no recitation of these phrases in claims 3 or 1.

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Claim 6 and by dependence claims 7 and 8 are vague and indefinite in the recitation of "A vector...comprising (a)forward mutagenic primer; (b) a reverse mutagenic primer....(c) a forward digestion site primer; (d) a reverse digestion site primer..." since it is not clear how a vector comprises a "primer", since a primer is a single stranded (isolated) fragment, while a vector is generally a circular double stranded DNA. In the interest of compact prosecution, it is assumed that "primer" could include a double stranded DNA molecule which is present within a vector, which may be a plasmid, which could serve as a primer for PCR type synthesis, when present in single stranded (either strand), linear form.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Bott et al. (WO 03/062381) or Poulouse et al. (WO 03/062380) (cited by applicants).

Bott or Poulouse disclose the method for direct transformation of a host cell comprising generating partially overlapping intermediate fragments by PCR, further comprising a first intermediate fragment and a second intermediate fragment, each comprising at least one mutated codon of interest, a flanking nucleotide sequence and a digestion site,; joining ends of said intermediate fragments to produce a linear product by fusion PCR, ligating of the linear product to create a circular product and incubating a host cell with said circular product (see pages 36-38, see Fig. 4, 5 of Bott; see pages 21-22, Fig. 4, 5 of Poulouse). The intermediate fragments comprise a forward and reverse mutagenic primer comprising a mutation and a flanking sequence. The digestion site may be an Apal digestion site. Bott et al. and Poulouse et al. disclose a vector comprising a forward and reverse mutagenic primer, having overlapping portion upstream and downstream of a mutagenic codon, and a forward and reverse digestion site primer, having digestion sites fused at end to form a circular polynucleotide sequence (see Figure on page 1, Fig. 5 of both). The forward and reverse digestion site primer are identical to those claimed (see page 37 of Bott, see page 21 of Poulouse).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Estell et al. (US Patent 5,182,204).

Estell et al. disclose a vector comprising a first and second mutagenic primer having overlapping portion upstream and downstream of a mutagenic codon, and a forward and reverse digestion primer which each have a restriction enzyme digestion site fused at end to form a circular polynucleotide site (see Fig. 1). Since the plasmid in Fig. 1 comprises a region of a gene having a mutation, this region comprises a forward and reverse mutagenic primer as recited in the claim. Since the plasmid comprises regions having restriction enzyme restriction sites, it would comprise a forward and reverse primer containing a restriction enzyme digestion site which is fused to form a circular DNA.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
3/24/09